

National Institutes of Health National Cancer Institute Bethesda, Maryland 20892

November 16, 1999

Memorandum of Recommendations on the Continuation of the Study of Leukemia among Chornobyl Cleanup Workers in Ukraine

On 15-16 November the Ukrainian and NCI Working Groups on Leukemia among Chornobyl Cleanup Workers met in Bethesda to consider the following agenda:

- 1) Review the draft final report on Phase I, the feasibility study preparatory to Phase II, a full-scale study of leukemia among Ukrainian cleanup workers, according to a 1996 bi-national agreement
- 2) Determine what modifications would seem necessary in the 1996 Phase II plans for a full study on the basis of Phase I and other considerations
 - 3) Recommend for or against a modified Phase II study
- 4) Consider what actions would be necessary to secure funding for Phase II and to maintain the continuity of funding the Scientific Center for Radiation Medicine where the investigation has been conducted.

On the basis of their review of the draft final report on Phase I the Working Groups judged a Phase II study to be feasible, provided that it could be combined with some additional work on methods of dose estimation.

In considering the provisions of the 1996 plans for Phase II, the results of the work in Phase I, and the transfer of Chornobyl-related research at NCI from the Division of Cancer Biology to the Division of Cancer Epidemiology and Genetics, the following changes in the 1996 plans for Phase II were suggested:

- 1) The epidemiologic design would be changed from the case-cohort approach to the case-control approach.
- 2) The target diseases of the investigation would be leukemia, myelodysplasia, and multiple myeloma (omitting lymphoma).
- 3) Research in molecular biology and on the pathogenesis on leukemia and lymphoma among high-dose subjects, with its requirement for banking tissue, would not be attempted at this time.
- 4) The major scientific objective of the study would remain: to elucidate the dose-response and time-response characteristics of the target diseases and to attempt an estimate of the dose-rate risk reduction factor in a comparison with the experience of the A-bomb survivors.
- 5) The study would be essentially retrospective in scope, covering the years 1987-2001, and would be conducted for 4 years, 2000-2003.

- 6) The role of cytogenetics in regard to dosimetry and the diagnosis of leukemia would be reduced in favor of physical dosimetry and dose reconstruction.
- 7) Attempts would be made to obtain the cleanup worker files of the military and the Ministry of Internal Affairs, both of which detailed large numbers of men to the cleanup site; otherwise the study cohort would be drawn from the official Chomobyl Registry of Ukraine.
- 8) Concurrently with the retrospective data collection the research on dosimetric methods would be continued in years 2000 and 2001.

Members of the two Working Groups unanimously recommended that support be found for Phase II as modified and the members of a small group to write the research proposal, headed by Dr Geoffrey Howe, were selected.

To maintain the established relationship between NCI and the Scientific Center for Radiation Medicine interim financial support from NCI will be required. It would bridge the period from 1 January, 2000, to the anticipated implementation date of the proposed Phase II study. The work of the next few months would consist of organizational and liaison activities to bring all six of the proposed oblasts into an operational network, of training selected members of the staff, and of organizing the proposed Leukemia Registry for the catchment area, as well intensifying the development of dosimetric methods.

Dr Gilbert W Beebe, Chairman

NCI Working Group

Dr Anatoly Ye Romanenko, Chairman

Ukrainian Working Group